25

- (1) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 375mg of nicotinic acid and having:
  - a nicotinic acid Cmax of about 3µg/ml; a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nictoinic acid of about 6µghr/ml.
- (2) An intermediate release nicotinic acid formulation of claim 1, wherein said nicotinic acid formulation is a tablet.

IPHOU:10485 32892-00023 Express Mail No.: EH364910166US

25

(3) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 375mg of nicotinic acid and having:

a nicotinuric acid Cmax of about 2µg/ml; a nicotinuric acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nictoinuric acid of about 10µghr/ml.

(4) An intermediate release nicotinic acid formulation of claim 3, wherein said nicotinic acid formulation is a tablet.

- (5) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 500mg of nicotinic acid and having:
  - a nicotinic acid Cmax in the range of from between about 1µg/ml and 10µg/ml; a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nictoinic acid in the range of from between about 2µghr/ml and about 34µghr/ml.
- (6) An intermediate release nicotinic acid formulation of claim 5, wherein the Cmax has a mean of about 4µg/ml and the AUC has a mean of about 9µghr/ml.
- (7) An intermediate release nicotinic acid formulation of claim 5, wherein said nicotinic acid formulation is a tablet.
- (8) An intermediate release nicotinic acid formulation of claim 6, wherein said nicotinic acid formulation is a tablet.

20

25

Express Mail No.: EH364910166US

IPHOU: 10485 32892-00023

- (9) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 500mg of nicotinic acid and having:
  - a nicotinuric acid Cmax in the range of from between about 2μg/ml and 3μg/ml; a nicotinuric acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nicotinuric acid in the range of from between about 6μghr/ml and about 16μghr/ml.
- (10) An intermediate release nicotinic acid formulation of claim 9, wherein the Cmax has a mean of about 2µg/ml and the AUC has a mean of about 9µghr/ml.
- (11) An intermediate release nicotinic acid formulation of claim 9, wherein said nicotinic acid formulation is a tablet.
- (12) An intermediate release nicotinic acid formulation of claim 10, wherein said nicotinic acid formulation is a tablet.

20

(13) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 750mg of nicotinic acid and having:

5

- a nicotinic acid Cmax in the range of from between about 8μg/ml and 9μg/ml; a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nictoinic acid in the range of from between about 21μghr/ml and about 22μghr/ml.
- (14) An intermediate release nicotinic acid formulation of claim 13, wherein the Cmax has a mean of about 8µg/ml and the AUC has a mean of about 21µghr/ml.
- (15) An intermediate release nicotinic acid formulation of claim 13, wherein said nicotinic acid formulation is a tablet.
- (16) An intermediate release nicotinic acid formulation of claim 14, wherein said nicotinic acid formulation is a tablet.

20

25

An intermediate release nicotinic acid formulation suitable for oral administration once-a-day

5

(17)

for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, intermediate release nicotinic acid formulation containing at least about 750mg of nicotinic acid and having:

a nicotinuric acid Cmax in the range of from between about 3µg/ml and 3.2µg/ml; a nicotinuric acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nicotinuric acid in the range of from between about 11µghr/ml and about

13µghr/ml.

- An intermediate release nicotinic acid formulation of claim 17, wherein the Cmax has a mean of about 3µg/ml and the AUC has a mean of about 12µghr/ml.
- An intermediate release nicotinic acid formulation of claim 17, wherein said nicotinic acid formulation is a tablet.
- (20)An intermediate release nicotinic acid formulation of claim 19, wherein said nicotinic acid formulation is a tablet.

20

25

Express Mail No.: EH364910166US

IPHOU:10485 32892-00023

(21) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 1000mg of nicotinic acid and having:

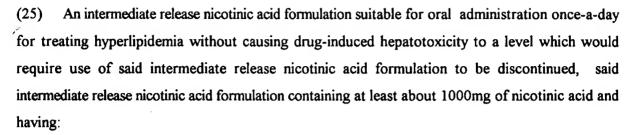
a nicotinic acid Cmax in the range of from between about 9µg/ml and 17µg/ml;

a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and

an AUC for nictoinic acid in the range of from between about 24µghr/ml and about 43µghr/ml.

- (22) An intermediate release nicotinic acid formulation of claim 21, wherein the Cmax has a mean of about 13µg/ml and the AUC has a mean of about 33µghr/ml.
- (23) An intermediate release nicotinic acid formulation of claim 21, wherein said nicotinic acid formulation is a tablet.
- (24) An intermediate release nicotinic acid formulation of claim 22, wherein said nicotinic acid formulation is a tablet.

20



a nicotinuric acid Cmax in the range of from between about 3μg/ml and 5μg/ml; a nicotinuric acid Tmax in the range of between about 5.6 hours and about 6 hours; and an AUC for nicotinuric acid in the range of from between about 12μghr/ml and about 19μghr/ml.

- (26) An intermediate release nicotinic acid formulation of claim 25, wherein the Cmax has a mean of about 4µg/ml and the AUC has a mean of about 15µghr/ml.
- (27) An intermediate release nicotinic acid formulation of claim 25, wherein said nicotinic acid formulation is a tablet.
- (28) An intermediate release nicotinic acid formulation of claim 26, wherein said nicotinic acid formulation is a tablet.

25